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AUG - 4 1983

Mr. Edwin L. Johnson
Director
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Johnson:

This is in response to your letter of June 24, 1983, requesting clarification on which of our agencies has jurisdiction to regulate pesticide residues in food resulting from the use of the pesticide as wood preservatives. We appreciate the opportunity to share our views on this matter with you.

Under the 1971 Environmental Protection Agency/Food and Drug Administration memorandum of understanding regarding matters of mutual responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), FDA would have primary responsibility for regulating preservatives used to treat wood that will come into contact with food or feed. A copy of this interagency agreement is enclosed for your convenience. Item 1.d of the memorandum of understanding assigns to EPA the responsibility for all petitions for food additive regulations for pesticides that are added to food contact materials to protect the food from pests. All other petitions for the use of pesticides in food contact materials are assigned to FDA (Item 2.c. of the memorandum of understanding). Because the substances that you inquire about (creosote, pentachlorophenol, and inorganic arsenicals) are used to protect the wood, these substances would be subject to regulation by FDA if the wood were to be used as a food contact material. However, registration and labeling of the preservatives themselves, which may be required by FIFRA, would fall under EPA's jurisdiction.

As you noted, FDA has issued a regulation (21 CFR 178.3800) for the use of pentachlorophenol at levels up to 50 parts per million in wood contacting raw agricultural products. We believe that the amount of pentachlorophenol that could migrate to such products from this use would be minimal. We would be concerned, however, about the use of pentachlorophenol treated wood under other conditions where the pentachlorophenol would be likely to migrate to food or animal feed such as silage. Such uses could result in chlorinated phenols or their contaminants being concentrated in the edible tissue of animals. The other two wood preservatives, creosote and inorganic arsenicals, are not presently authorized for any uses whereby they may become components of food.

Whether food that contains arsenic is adulterated can only be determined on a case-by-case basis. For example, if the agency is aware that the arsenic in the food is the result of a purposeful use of the arsenic, FDA can decide whether the food is adulterated on the basis of whether there is a food additive regulation that authorizes the particular use. Because no food additive regulation authorizes the use of arsenic as a preservative in wood that is to be used as food contact material, any arsenic that migrates to food from the wood

as a result of that use would adulterate the food (see 21 U.S.C. 342(a)(2)(C)). On the other hand, when the agency cannot establish that the arsenic is present as the result of a purposeful use, whether the food is adulterated by the arsenic depends upon a number of factors, including the amount of arsenic that is present, and the effect that that amount of arsenic would have on health (see 21 U.S.C. 342(a)(1)).

FDA does not believe that it would be appropriate to propose on our own initiative to adopt a food additive regulation authorizing the use of arsenic as a preservative in wood. Even with the test protocol enclosed with your letter, the agency does not have sufficient information to propose such a regulation. For example, because the agency does not have definitive information on the ways in which preserved wood can contact food, FDA is unable to determine whether the examples submitted in the test protocol are illustrative or complete. The agency has also been unable to determine whether these examples represent worst case exposure situations. In addition, the agency has been unable to find a definition of which inorganic arsenicals (referred to as salt- and acid-based CCA and ACA) are under consideration in the test protocol. Thus, the most efficient course would be for the industry to submit a petition on the use of arsenic as a wood preservative.

In summary, preserved wood cannot be used under circumstances where the preservative may become a component of food or feed unless such use has been shown to be safe and a food additive regulation promulgated under section 409 of the FFDCRA prescribes safe use. We strongly urge anyone seeking to amend the food additive regulations to provide for that use to discuss their plans with us before submitting a petition. Such a petition must include complete information on the identity of the preservative, the results of validated migration experiments suitable for the conditions of use, and a toxicity profile of those substances expected to become components of food.

We noted that the CIS advised that pentachlorophenol or creosote preserved wood should be sealed if used in a house. We would suggest that consideration be given to including a similar statement concerning barns, stalls, stables and other buildings used to house animals.

We suggest that anyone interested in further information on this issue contact the following persons:

For articles contacting food:

Mr. Gerard McCowin, Director
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Control
↑
Petitions Branch

Dr. George Pauli or Consumer Safety Officer

For articles contacting animal feed:

Mr. Edward Ballitch
Division of Compliance
~~Center for~~ Veterinary Medicine
Food and Drug Administration
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(301) 443-4940

> *George*
D. Graver (HFV-220)
Division of Animal Feeds
443-4438

If we can be of further assistance, please do not hesitate to contact us.

Sincerely yours,

Joseph P. Hile
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

Enclosure